FORM PTO-1390 **U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE**
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 980166US/II

U.S. APPLN. NO. (If known, see 37 CFR 1.5) 09/890583

INTERNATIONAL APPLICATION NO.:	INTERNATIONAL FILING DATE:	PRIORITY DATE CLAIMED:
PCT/SE00/00113	20 JANUARY 2000	2 FEBRUARY 1999

TITLE OF INVENTION: LIQUID SEPARATOR WITH HOLDER UNIT

APPLICANT(S) FOR DO/EO/US: Anders ECKERBOM and Per LINDESTAM

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] has been transmitted by the International Bureau. (see attached copy of PCT/IB/308)
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Item 11. to 16. below concern document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A **FIRST** preliminary amendment.
    [ ] A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT/IPEA/409)
INTERNATIONAL SEARCH REPORT (PCT/ISA/210) & 2 cited references
ABSTRACT of the disclosure on a separate sheet
APPLICATION DATA SHEET

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 09/890583	INTERNATIONAL APPLICATION NO. PCT/SE00/00113	ATTORNEY'S DOCKET NO. 980166US/II

	CALCULATIONS PTO USE ONLY	
17. [X] The following fees are submitted:		
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):		
Neither international preliminary examination fee (37 CFR1.482) nor international search fee (37 CFR1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... $ 1,000.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... $ 860.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... $ 710.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... $ 690.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... $ 100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 1,000.00	
Surcharge of $130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 1,130.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$
Total claims	7 - 20 =	0	X $18.00	$
Independent claims	1 - 3 =	0	X $80.00	$
MULTIPLE DEPENDENT CLAIMS(S) (if applicable)			+ $270.00	$

TOTAL OF ABOVE CALCULATIONS =	$ 1,130.00	
Reduction of ½, if applicant is entitled to Small Entity status under 37 CFR 1.27. +	$	
SUBTOTAL =	$ 1,130.00	
Processing fee of $130 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR1.49(f)).	$	
TOTAL NATIONAL FEE =	$ 1,130.00	
Fee for recording the enclosed assignment (37 CFR1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +	$	
TOTAL FEES ENCLOSED =	$ 1,130.00	
	Amount to be refunded:	
	charged:	

a. [X] A check in the amount of $ **1,130.00** to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. **25-0120** in the amount of $ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required by 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. **25-0120**. A duplicate copy of this sheet is enclosed.

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August 2, 2001

By Benoît Castel
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Anders ECKERBOM et al. Box PCT

Serial No. (unknown) Application Branch

Filed herewith

LIQUID SEPARATOR
WITH HOLDER UNIT

PRELIMINARY AMENDMENT

Commissioner for Patents

Washington, D.C. 20231

Sir:

Prior to the first Official Action and calculation of the filing fee, please amend the above-identified application as follows:

IN THE CLAIMS:

Amend claim 3 as follows:

--3. (Amended) A liquid separator according to Claim 2, **characterised** in that the water trap (1) includes two connection passageways (9, 10), and in that the holder unit (2) includes two connection devices (15, 16).--

Amend claim 4 as follows:

--4. (Amended) A liquid separator according any Claim 1, **characterised** in that the holder unit (2) includes a first electric contact element (18) which functions to detect the presence of a liquid trap (1) in the holder unit and to stop the flow of sample gas to the analysis instrument when no water trap is fitted in the holder unit.--

Amend claim 5 as follows:

--5. (Amended) A liquid separator according to Claim 1, **characterised** in that the holder unit (2) includes a second electric contact element (17) which functions to detect the type of water trap (1) fitted in the holder unit and to adjust the analysis instrument in accordance with the type of water trap used.--

Amend claim 7 as follows:

--7. (Amended) A liquid separator according to Claim 1, **characterised** in that the water trap (1) is intended for one-time use only.--

R E M A R K S

The above changes in the claims merely place this national stage application in the same condition as it was during Chapter II of the international stage, with the multiple dependencies being removed.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

YOUNG & THOMPSON

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August 2, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amend claim 3 as follows:

--3. (Amended) A liquid separator according to ~~Claims 1 and~~ Claim 2, **characterised** in that the water trap (1) includes two connection passageways (9, 10), and in that the holder unit (2) includes two connection devices (15, 16).--

Amend claim 4 as follows:

--4. (Amended) A liquid separator according any ~~one of the preceding Claims~~ Claim 1, **characterised** in that the holder unit (2) includes a first electric contact element (18) which functions to detect the presence of a liquid trap (1) in the holder unit and to stop the flow of sample gas to the analysis instrument when no water trap is fitted in the holder unit.--

Amend claim 5 as follows:

--5. (Amended) A liquid separator according to ~~any one of the preceding Claims~~ Claim 1, **characterised** in that the holder unit (2) includes a second electric contact element (17) which functions to detect the type of water trap (1) fitted in the holder unit and to adjust the analysis instrument in accordance with the type of water trap used.--

Amend claim 7 as follows:

--7. (Amended) A liquid separator according to ~~any one of the preceding Claims~~ Claim 1, **characterised** in that the water trap (1) is intended for one-time use only.--

LIQUID SEPARATOR WITH HOLDER UNIT

The present invention relates to a liquid separator for separating liquid from gases, and particularly for separating liquids from expiration gases in medical analysis instruments.

When a gas sample from expiration gases is led in a patient circuit to an analysis instrument, it is unavoidable that moisture, secretion, blood, bacteria, etc., are liable to accompany the sample. As the temperature falls when the gas sample is led from the patient circuit to the analysis instrument, moisture present in the gas precipitates in the form of water droplets. Should water, blood or secretion enter the analysis instrument, there is a serious risk that the instrument will be permanently damaged, and consequently various protective solutions for preventing such contamination have been proposed in the art.

The simplest method of avoiding the ingress of bacteria, blood and secretion into the gas sample is to place a hydrophobic bacteria filter in the orifice of the sampling conduit proximal to the patient circuit. One drawback with this solution resides in the difficulty of obtaining a filter surface, which is sufficiently large to prevent the rise time of the gas measuring process from being impaired. A filter that has a small surface area will quickly become blocked and therewith result in an interruption in the gas monitoring process.

The presence of a bacteria filter in the orifice of the sampling conduit will not solve the moisture problem, because the moisture does not precipitate from the sample until the

sample is downstream of the filter. One solution to this problem is to use a special hose material, Nafion®, which allows moisture to wander freely through the hose wall. This material, however, is very expensive which makes it difficult to obtain viable products when using said material.

Alternatively, water droplets, and possibly also secretion, can be separated from expiration gas in a water trap. A positive, inexpensive and effective separator can be obtained, by combining the water trap with a bacteria filter. However, one drawback with this solution is that the rise time of the gas measuring process will be seriously impaired unless the water trap is adapted with respect to the volume of gas that shall be processed at that particular time.

The need for a short rise time is particularly accentuated when measuring the expiration gas of newly born infants, e.g. neonatal patients. Small children usually have a considerably higher respiration rate than adults. 40-60 breaths per minute is normal for such infants, as compared to about 12 breaths per minute for adults. Thus, in this case the gas sampling system must have a pneumatic rise time of well above 0.5 s in order to carry out a correct gas analysis with respect to time, a rise time of 200 ms being an appropriate value in this respect.

The pneumatic rise time of the gas sampling system is essentially inversely proportional to the sampling flow, in other words a high rate of flow results in a short rise time. Respiration volumes of several litres are normal in the case of adult patients, which enables sample flow rates in the order of 200-300 ml/min to be used without influencing the respiratory circuit. However, in the case of neonatal patients,

which have respiratory volumes in the order of decilitres, it is necessary to lower the rate of flow to a minimum. 50 ml/min is a normal flow rate in this latter case. Consequently, when the need for a short rise time is greatest, the possibilities of achieving such a rise time are the worst.

In addition to needing to extract moisture, bacteria, etc., from the expiration gas of a patient, it is also necessary to protect the analysis instrument from dirt and other contaminants present in the ambient air. Many gas analysis instruments have long warm-up times, meaning that the instrument is normally never switched off. Consequently, if the instrument is left switched on for a long period of time in the absence of a protective filter, the measuring chamber of the analyser will gradually become dirty with progressively poorer performances as a result.

Water traps have been the solution that has been used to increasing extents to eliminate moisture in gas samples. EP-A2-0 549 266 teaches a method of extracting both moisture and other foreign particles with the aid of a hydrophobic bacteria filter. In the case of the water trap described in this prior publication, the gas sample is passed through a passageway that is divided in an upper half and a lower half of the hydrophobic filter. The moist gas sample is led into the front edge of the lower half of a passageway and is caused to exit by applying a strong sub-pressure to an opening in the rear edge of the upper half of said passageway. The liquid extracted by this arrangement is led away by applying a weak sub-pressure to an opening in the rear edge of the lower half of the passageway.

One drawback with this known water trap is that it requires a relatively large filter area, about 1 cm^2, in order to ensure that the product will have a sufficient length of life. The length of the passageway is limited chiefly by the desire to obtain the smallest possible unit. A length of about 3.5 cm has been found suitable. Consequently, a passageway diameter of about 3 mm is needed in order to obtain an effective filter surface. Hoses used for gas sampling purposes, however, will normally have an inner diameter of about 1.4-1.5 mm, meaning that eddy currents are generated and impaired rise time obtained when the gas sample reaches the larger diameter of the passageway.

Accordingly, the object of the present invention is to provide a liquid separator that avoids the aforesaid drawback with the earlier known water trap.

This object is achieved with an inventive liquid separator that has the characteristic features set forth in the accompanying Claims.

There is provided in accordance with the invention a liquid separator for extracting liquid from gases, said separator comprising a water trap that includes a container, a connection for incoming gas flows, a separation chamber that includes a filter, and at least one connection passageway for conducting separated gas to an analysis instrument, wherein the water trap can be attached removably to a holder unit connected to the analysis instrument, and wherein the holder unit includes connection means for connection of the connecting passageway.

The invention also enables water traps of different sizes to be used for adults and for children, with automatic switching of the analysis instrument in accordance with the size of water trap used.

The invention will now be described with reference to a non-limiting exemplifying embodiment thereof and also with reference to the accompanying drawings, in which **Fig. 1** is a perspective view of an inventive liquid separator, showing the water trap and the holder unit separated from one another; **Fig. 2** is a perspective exploded view of the water trap shown in Fig. 1; and **Fig. 3** is a perspective exploded view of the holder unit shown in Fig. 1.

The inventive liquid separator comprises two main parts in the form of a water trap 1 and a holder unit 2. The holder unit 2 is a part that can normally be firmly fitted to the instrument (not shown) used to analyse expiration gas. The water trap 1 is a disposable product that is preferably found in two different sizes or two different designs, one for adult patients and one for neonatal patients.

The water trap 1 includes a container 3 located beneath a separation chamber 4 provided with a connection 5 for receiving a gas flow incoming from the patient. The separation chamber includes a liquid passageway 6 and a filter 7 positioned above said passageway, for instance a bacteria filter. Located above the separation chamber 4 and connecting to the other side of the filter 7 is an upper chamber part 8 that includes a gas passageway (not shown) corresponding to the liquid passageway 6 in the separation chamber and leading to connection passageways 9, 10 by means of which the water trap can be connected to the holder unit 2 and to the analysis

instrument respectively. The upper chamber part 8 is covered by a hood or cap 11. The separation chamber 4 is fitted externally with locking tabs 12 which enable the water trap 1 to be snapped firmly to the holder unit 2.

The separation chamber 4 is preferably fixed permanently to the upper chamber part 8, for instance ultrasound welded thereto. The filter 7, which is inserted between the separation chamber and the upper chamber part 8, may be of the PTFE kind and has a pore size of about 0.5 µm and may be sealed with the aid of a labyrinth seal formed in the separation chamber and the upper chamber part. The container 3 of the water trap is adapted so as to be removable from the separation chamber 4 and therewith enable liquid collected in the container to be emptied therefrom.

The holder unit 2 includes a cavity 13 in which part of the water trap 1 can be accommodated. The holder unit includes locking apertures 14 which receive the locking tabs 12 on the water trap and therewith lock the trap 1 firmly in the holder unit. Two connection devices 15, 16 are provided behind the cavity 13 for receiving the connection passageways of the water trap 1. These connection devices 15, 16 are connected to hoses passing to the analysis instrument. Two electric contact elements 17, 18 are provided in the rear edge of the cavity 13 and are activated by insertion of a water trap 1 into the cavity 13 of the holder unit 2.

The electric contact elements 17, 18 are adapted so that one contact element will detect the presence of a water trap in the holder unit, wherewith when the water trap 1 is removed from the holder unit 2 the contact element will function to immediately stop the flow to the analysis instrument, or will

stop said flow after a certain time delay, so that no air and possible contaminants will be sucked into the instrument and contaminate the same. The other electric contact element is adapted to detect the type of water trap inserted into the holder unit. The two different types of water trap mentioned above may be designed differently at the contact region with said other electric contact element, for instance such that when using a water trap intended for children the contact will be pressed in, while providing a water trap intended for adult patients with an aperture which will mean that said other electric contact will not be pressed in when fitting said trap. The second electric contact element will then be arranged so that when it is pressed-in by fitting a water trap intended for neonatal patients, the analysis instrument will be switched to a mode in which it operates with a lower rate of flow.

The two connection passageways 9, 10 are connected to the connection devices 15, 16 of the holder unit 2 so that both a main flow that passes from the water trap to the analysis instrument and a secondary flow that passes through the container of the water trap can be obtained.

The main difference between the two water trap embodiments is that one is intended for adult patients and has a passageway width of about 3 mm, whereas the neonatal model has a passageway width of about 1.4 mm. The smaller passageway width in the neonatal model means that the rise time will be much quicker than in the case of the adult model. In this case, the problems normally occurring with shorter product life lengths are compensated for by using a lower rate of sample flow.

Because the type of water trap used can be identified, the analysis instrument can be set automatically to choose an optimal rate of sample flow for respective models through the medium of said electric contact elements. In the case of the adult model, there is normally used a flow rate in the order of 200-300 ml/min, whereas a flow rate of about 50 ml/min is normally used in the case of the neonatal model. Switching between these flow rates can thus take place fully automatically, without the risk of a wrong setting being made manually.

CLAIMS

1. A liquid separator for separating liquid from gases and comprising a water trap (1) that includes a container (3), a connection (5) for incoming gas flow, a separation chamber (4) that includes a filter (7), and at least one connection passageway (9, 10) for leading liquid-free gas to an analysis instrument, **characterised** in that the water trap (1) can be removably fitted in a holder unit (2) connected to the analysis instrument; and in that the holder unit (2) is provided with connection devices (15, 16) for accommodating the connection passageway (9, 10).

2. A liquid separator according to Claim 1, **characterised** in that the connection device (15, 16) is a quick-fastener device for connection to the connection passageway (9, 10).

3. A liquid separator according to Claims 1 and 2, **characterised** in that the water trap (1) includes two connection passageways (9, 10), and in that the holder unit (2) includes two connection devices (15, 16).

4. A liquid separator according to any one of the preceding Claims, **characterised** in that the holder unit (2) includes a first electric contact element (18) which functions to detect the presence of a liquid trap (1) in the holder unit and to stop the flow of sample gas to the analysis instrument when no water trap is fitted in the holder unit.

5. A liquid separator according to any one of the preceding Claims, **characterised** in that the holder unit (2) includes a second electric contact element (17) which functions to detect the type of water trap (1) fitted in the holder unit and

to adjust the analysis instrument in accordance with the type of water trap used.

6. A liquid separator according to Claim 5, **characterised** in that the water trap (1) is designed in different sizes for infants and adults; and in that one size includes means for actuating the second electric contact element (17) of the holder unit.

7. A liquid separator according to any one of the preceding Claims, **characterised** in that the water trap (1) is intended for one-time use only.

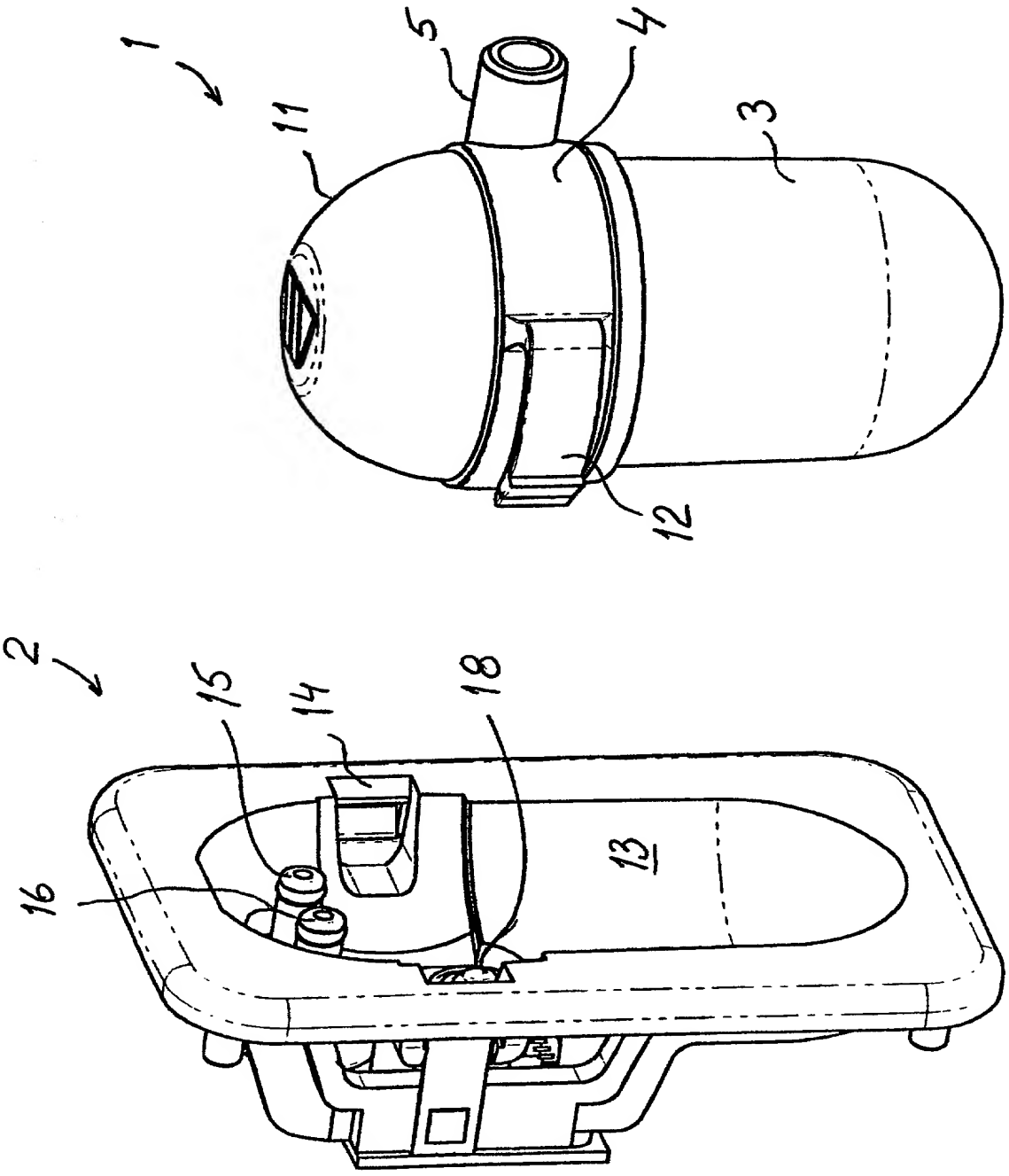

Fig. 1

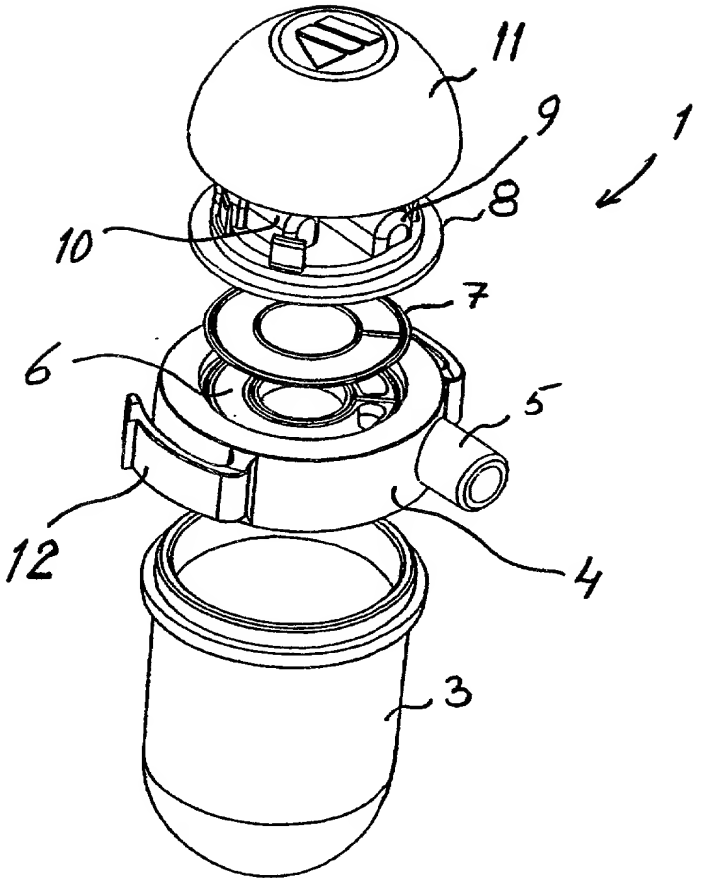

Fig. 2

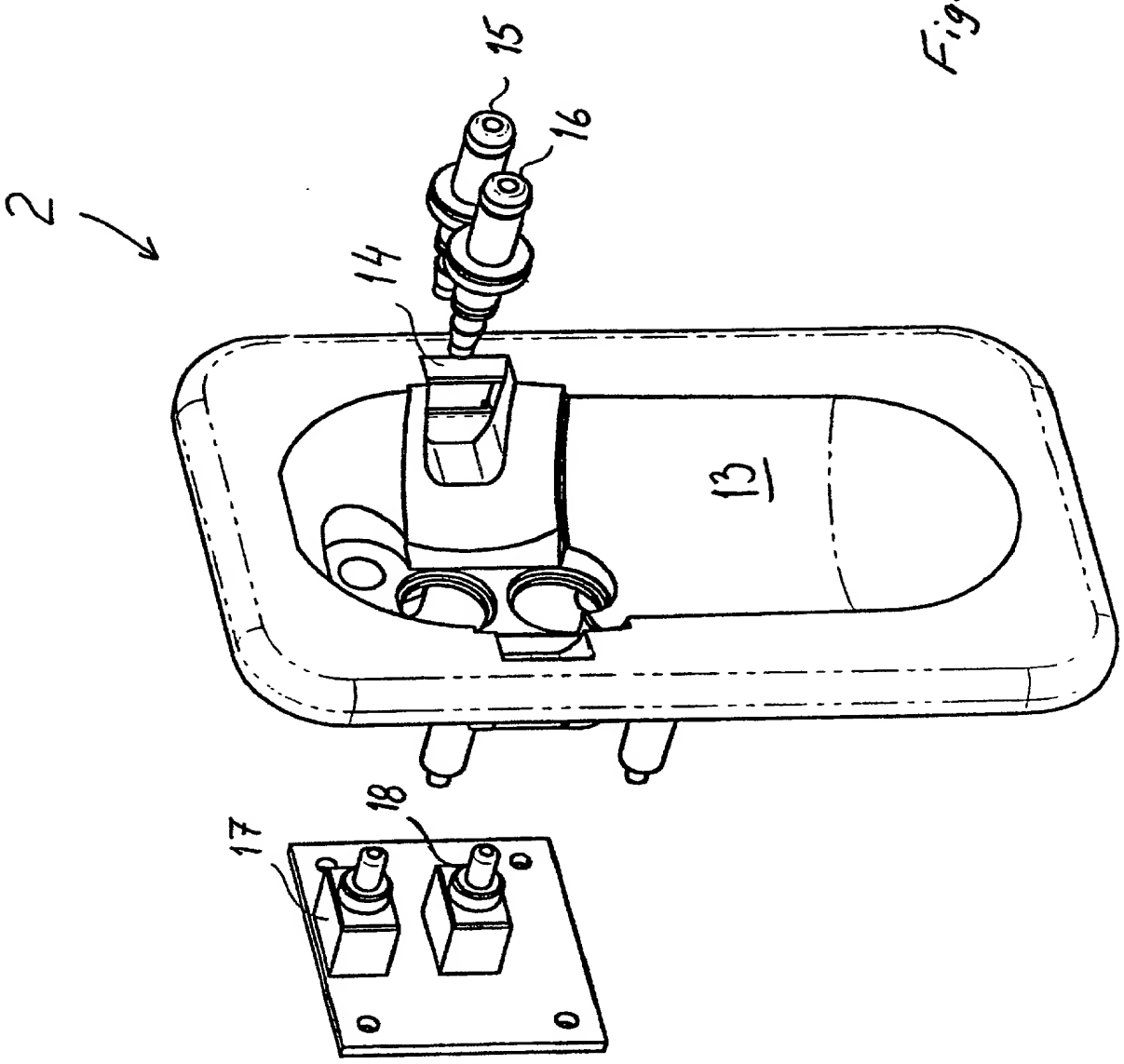

Fig. 3

Ref. 980166US

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

LIQUID SEPARATOR WITH HOLDER UNIT

the specification of which: *(check one)*

REGULAR OR DESIGN APPLICATION

[ ] is attached hereto.

[ ] was filed on as application Serial No. and was amended on (if applicable).

PCT FILED APPLICATION ENTERING NATIONAL STAGE

[X] was described and claimed in International application PCT/SE00/00113 filed on 20 January 2000 and as amended on (if any).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

PRIORITY CLAIM

I hereby claim foreign priority benefits under 35 USC 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN APPLICATION(S)

Country	Application Number	Date of Filing (day, month, year)	Priority Claimed
Sweden	**9900351-9**	**2 February 1999**	**yes**

(Complete this part only if this is a continuing application.)

I hereby claim the benefit under 35 USC 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 USC 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.) (Filing Date) (Status--patented, pending, abandoned)

POWER OF ATTORNEY

The undersigned hereby authorizes the U.S. attorney or agent named herein to accept and follow instructions from **Norens Patentbyra AB** as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the U.S. attorney or agent and the undersigned. In the event of a change in the persons from whom instructions may be taken, the U.S. attorney or agent named herein will be so notified by the undersigned.

As a named inventor, I hereby appoint the registered patent attorneys represented by Customer No. **000466** to prosecute this application and transact all business in the Patent and Trademark Office connected therewith, including: **Robert J. PATCH, Reg. No. 17,355, Andrew J. PATCH, Reg. No. 32,925, Robert F. HARGEST, Reg. No. 25,590, Benoît CASTEL, Reg. No. 35,041, Eric JENSEN, Reg. No. 37,855, Thomas W. PERKINS, Reg. No. 33,027, and Roland E. LONG, Jr., Reg. No. 41,949,**

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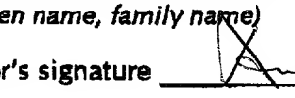
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00 Full name of sole or first inventor: **Anders ECKERBOM**
(given name, family name)

Inventor's signature  Date 01 08 14

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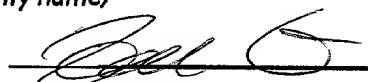
2-00 Full name of second joint inventor, if any: **Per LINDESTAM**
(given name, family name)

Inventor's signature  Date 010814

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